

Filed: Herewith

Page 3

§120 hereinabove. Applicants submit herewith a new Declaration which includes reference to the two aforementioned U.S. Serial Nos. as applications to which the applicants now claim priority under 35 U.S.C. §120. Therefore, applicants request that the Examiner enter this amendment.

Supplemental Information Disclosure Statement

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants would like to direct the Examiner's attention to the following documents, which are listed hereinbelow and again listed on Form PTO-1449 attached hereto as Exhibit B. Copies of the documents listed below are attached hereto as Exhibits 1-32 except that copies of Exhibits 2, 6, 7, 12, 17, 23 and 25 will be submitted shortly.

- Brett, J, et al., (1993) "Survey of the distribution of a newly-characterized receptor for AGEs in tissues" Am. J. Pathol, 143:1699-1712.
- 2. Connolly ES, Winfree CJ, Stern DM, Solomon RA, Pinsky DJ: Procedural and strain-related variables significantly affect outcome in a murine model of focal cerebral ischemia. Neurosurg 1996;38:523-532.
- 3. Gibbons, G. H. and V. J. Dzau. (1996). Molecular therapies for vascular diseases. <u>Science</u> 272: 689-693.

Filed: Herewith

Page 4

- 4. Hori, et al. "The Receptor for Advanced Glycation Endproducts: Implications for the Development of Diabetic Vascular Disease. Fundam. Clin. Cardiol." In: The Endothelium in Clinical Practice. January 1997, Chapter 11, pages 311-329.
- 5. Khoury, J., et al., (1994) "Macrophages adhere to glucose-modified basement membrane via their scavenger receptors" J. Biol. Chem., 269:10197-10200.
- 6. Kindy, S. Mark and Rader, J. Daniel (1998) "Reduction in Amyloid A Amyloid Formation in Apolipoprotein-E-Deficient Mice," American Journal of Pathology 152:1387-1395.
- 7. Marui, N., et al. (1993) "VCAM-1 gene transcription and expression are regulated through an oxidant-sensitive mechanism in human vascular endothelial cells" J. Clin. Invest., 92:1866-1874.
- 8. Morser et al., **U.S. Patent No. 5,864,018**, filing date April 16, 1996.
- 9. Morser et al. PCT International Application No. PCT/EP97/01834, filed April 11, 1997, published October 23, 1997; Publication No. WO 97/39125, Antibodies Against the Advanced Glycation Endproduct Receptor and Uses Thereof.
- 10. Morser et al. PCT International Application No.

Filed: Herewith

Page 5

PCT/EP97/01832, filed 11 April 1997, published October 23, 1997, Publication No. WO 97/39121, Advanced Glycation Endproduct Receptor Peptides and Uses Thereof.

- 11. Nakamura, Y. et al. (1993) Immunohistochemical localization of advanced glycosylation endproducts in coronary atheroma and cardiac tissue in diabetes mellitus. Am. J. Pathol. 143(6):1649~1656.
- 12. Nakashima Y, Plump A, Raines E, Breslow J, Ross R:
 ApoE-deficient mice develop lesions of all phases of
 atherosclerosis throughout the arterial tree. Arterioscler
 Thromb 1994;141:133-140.
- 13. Neeper, M., et al. (1992). Cloning and expression of a cell surface receptor for advanced glycosylation end products of proteins. J. Biol. Chem. 267: 14998-15004.
- 14. Palinski, W. et al. (1995) Immunological evidence for the presence of advanced glycation end products in atherosclerotic lesions of euglycemic rabbits. Arterioscl.

 Thromb. And Vasc. Biol. 15(5):571-582.
- 15. Park, L., et al. (1998) "Suppression of accelerated diabetic atherosclerosis by soluble Receptor for AGE (sRAGE)" Nature Medicine, 4:1025-1031.
- 16. Park, L., et al. (1997). A murine model of accelerated

Filed: Herewith

Page 6

diabetic atherosclerosis: suppression by soluble receptor for advanced glycation endproducts. <u>Circulation Supplement</u>.

Abstract 3079

- 17. Ritthaler, et al. (1995) Expression of receptors for advanced glycation end products in peripheral occulsive vascular disease. Am. J. Path. 146:688-694.
- 18. Schmidt, A. M. et al. (1993) Regulation of human mononuclear phagocyte migration by cell surface-binding proteins for advanced glycation end products. J. Clin. Invest. 92:2155-2168.
- 19. Schmidt, A. M., et al. (1997) "The V-Domain of Receptor for Advanced Glycation Endproducts (RAGE) mediates binding of AGEs: a novel target for therapy of diabetes" Circulation Supplement, 96:#194, p. I -37.
- 20. Schmidt, A-M, et al. (1994) "Cellular receptors for advanced glycation end products" Arterioscler. Thromb., 14:1521-1528.
- 21. Schmidt, A. M., et al (1995) "The Dark Side of Glucose (News and Views)" Nature Medicine, 1:1002-1004.
- 22. Schmidt, A-M, et al. (1994) "Receptor for advanced glycation endproducts (AGEs) has a central role in vessel wall interactions and gene activation in response to circulating AGE proteins" Proc. Natl. Acad. Sci. (USA), 91:8807-8811.

Filed: Herewith

Page 7

- 23. Schmidt A-M, Yan S-D, Wautier J-L, Stern DM: Activation of RAGE: a mechanism for chronic dysfunction in diabetic vasculopathy and atherosclerosis. Circ Res 1999;84:489-497.
- 24. Stern et al., PCT International Publication No. WO 97/26913, published July 31, 1997, PCT International Application No. PCT/US97/00857 (Attny Dkt 48316-PCT).
- 25. Stern, D., AM Schmidt and Jun Wu PCT International Publication No. WO/98/22138 Published May 28, 1998, PCT International Application No. PCT/US97/21197 filed November 12, 1997 A Method For Treating Symptoms Of Diabetes In A Subject (Attny Dkt. 50159-PCT).
- 26. U.S. Patent No. 5,688,653, November 18, 1997 (Ulrich, et al.).
- 27. Vlassara et al., US Patent 5,585,344.
- 28. Vlassara, H., et al. (1995) "Identification of Galectin-2 as a high affinity binding protein for Advanced Glycation Endproducts (AGE): a new member of the AGE-Receptor complex"

 Molecular Medicine, 1:634-646.
- 29. Vlassara, H., et al. (1994). Pathogenic effects of advanced glycosylation: biochemical, biologic, and clinical implications for diabetes and aging. <u>Lab. Invest.</u> 70: 138-

Filed: Herewith

Page 8

151.

- 30. Wautier, J. L., et al. (1996) "Receptor-mediated endothelial dysfunction in diabetic vasculopathy: sRAGE blocks hyperpermeability in diabetic rats" J. Clin. Invest., 97 (1):238-243.
- 31. Wautier, J.-L., et al. (1996). Interaction of diabetic erythrocytes bearing advanced glycation endproducts with the endothelial receptor AGE induces generation of reactive oxygen intermediates and cellular dysfunction. <u>Circulation Supplement</u> 94(8): #4139.
- 32. Yan, S-D., et al. (1994) "Enhanced cellular oxidant stress by the interaction of advanced glycation endproducts with their receptors/binding proteins" J. Biol. Chem., 269:9889-9897.

The fee for filing a Supplemental Information Disclosure Statement under 37 C.F.R. §1.17(p) is \$180.00 and a check including this amount is enclosed herewith. Applicants request the Examiner make these references of record.

Early and favorable action is respectfully requested.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone at the number

David M. Stern and Ann Marie Schmidt U.S. Serial No.: CPA2 of 08/905,709 Filed: Herewith Page 9

provided below.

No fee other than the \$355.00 CPA filing fee and the \$180.00 IDS fee, is deemed necessary in connection with the filing of this CPA, Supplemental IDS and Preliminary Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

John P. White

Registration No. 28,678

Jane M. Love

Registration No. 42,812

Attorneys for Applicants

Cooper & Dunham, LLP

1185 Avenue of the Americas

New York, New York 10036

(212) 278-0400